

REMARKS

Claims 1-49 are all the claims pending in the application.

Claim 1 has been amended to more clearly define the formulation of the present invention.

Claims 2 and 6 have been amended to be rewritten in independent form. Since the Examiner has indicated on page 2 of the Office Action that claims 1-20 are under examination¹ and has not rejected claims 2, 6 or the claims depending therefrom, it is respectfully submitted that these claims are patentable and allowance of these claims is respectfully requested.

Entry of the above amendments is respectfully requested.

I. Response to Rejection of Claims 1 and 10-13 under 35 U.S.C. § 102

Claims 1 and 10-13 remain rejected under 35 U.S.C. 102(b) or at least 102 (a) as allegedly being anticipated by King Bio Natural Medicines, as evidenced by Dr. Frank J. King (V) and Internet Archive Wayback Machine (W).

Applicant respectfully traverses the rejections and submits that King Bio Natural Medicines do not disclose the present invention for the reasons of record and for the following reasons.

The Examiner asserts that the claims are not limited to an external topical formulation. However, claim 1 was amended to recite "A formulation for topical use," and has been further amended to recite "A topical formulation." It is respectfully submitted that the preamble should

¹ In the Office Action Summary, claims 2-9 and 15-18 are indicated as being withdrawn, however, in view of the Examiner's indication that claims 1-20 are under examination, correction of the Office Action Summary is requested.

be given patentable weight. Specifically, "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See MPEP § 2111.02. Further, "any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation" (emphasis added). See MPEP § 2111.02(I). In this case, the recitation of a topical application is a structural element recited in the preamble of the claim and this element gives the claim life and meaning.

Further, in *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951), the preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article. Similarly in the present case, it is by the phrase "topical formulation" in the present claims that it can be known that the subject matter defined by the claims is comprised as a topical formulation and every union of active and non-active ingredients is not a topical formulation.

In addition, the Examiner asserts "that there is no ingredients contained therein the prior art reference to preclude use thereof for topical use." Thus, the Examiner considers the ingredients in the "911 Stress Control 2 oz Liquid" ("the 911 Product") as not being precluded for

use in a topical formulation. Although the 911 Product comprises some of the ingredients contained in the formulation of claims 1 and 10-13, it is an oral formulation, not a topical formulation. This is clear from the indications for the 911 Product and the other ingredients therein that the formulation is an oral formulation.

First, King Bio Natural Medicines lists the following indications for use: "For fast relief of nervous tension, minor anxieties, fearfulness, over-sensitivity; effective support during high pressure and stressful situations." These are all internal emotional-mental states, and there is no mention of external pain relief for pains, aches, bruises, inflammation, etc. Second, King Bio Natural Medicines lists the following ingredients for the 911 Product: Actonitum Napellus, Apis Mellifica, Arnica Montana, Arsenicum Album, Belladonna, Bellis Perennis, Bryonia Alba, Calendula Officinalis, Chamomilla, Cistus Canadensis, Clematis Erecta, Ferrum Phosphoricum, Histaminum, Hypericum perforatum, Ignatia Amara, Impatiens Glandulifera Flos, Ornithogalum Umbellatum, Passiflora Incarnata, Phosphorus, Prunus Cerasifera Flos, Rhus Toxicodendron, Sulphur, Symphytum Officinale, Veratrum Album. Among these ingredients, there are in fact eight drug ingredients that are **precluded** for topical use, and are classified as "N.A." by the Homeopathic Pharmacopoeia of the United States ("HPUS"), which is one of the three official compendia of the United States. The official committees of the Homeopathic Pharmacopoeia Convention of the U.S. publishes the various dispensing potencies of the individual drugs for various applications and lists "N.A." for various drugs indicating "Potency level data is not applicable for the particular drug." Under the HPUS guidelines, the 911 Product contains eight drugs precluded as N.A.'s relative to external use: Cistus Canadensis, Clematis Erecta, Histaminum, Ignatia Amara, Ornithogalum Umbellatum, Passiflora Incarnata, Prunus Cerasifera Flos, Veratrum

Album, and these ingredients could not lawfully nor have meaningful potency usage in a topical formulation.

Thus, the 911 Product is clearly not a topical formulation and is different from the topical formulation of the present invention.

For the above reasons, King Bio Natural Medicines does not anticipate claims 1 and 10-13. Accordingly, withdrawal of the rejection is respectfully requested.

II. Response to Rejection of Claims 1 and 11-13 under 35 U.S.C. § 102

Claims 1 and 11-13 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Traumeel® (AN, Product Label for Traumeel®. Homeopathic Ointment, 1995.) and Epicure (AM, Product Label for Unscented Epicure Crystal Sports Cream. Natural Homeopathic Pain Reliever, 1996).

Applicant respectfully traverses the rejection and submits that the cited references do not anticipate the present invention.

The Examiner asserts that Traumeel® teaches a formulation for topical use comprising ingredients and a base suitable for topical penetration of the skin, wherein the herbal active ingredients comprise: homeopathic preparations of Bellis perennis, Calendula officinalis, Hamamelis Virginiana, Arnica Montana, Hypericum Perforatum and Aconitum Napellus. In addition, the Examiner asserts that Epicure teaches a formulation, Epicure Crystal, for topical use comprising herbal active ingredients and a gel base suitable for topical penetration of the skin, wherein the herbal active ingredients comprise: homeopathic preparations of Bellis Perennis, Arnica Montana, Hypericum Perforatum, Aconitum Napellus, Ledum Palustre, and Ruta Graveolens.

The Examiner appears to consider Traumeel® and Epicure as both containing "Arnica

Montana.” However, Traumeel® and Epicure do not contain Arnica Montana, an official homeopathic drug, but rather they contain Arnica Montana Radix. Arnica Montana and Arnica Montana Radix are two different drugs. The Homeopathic Pharmacopoeia of the United States Revision Service, the official legal source for homeopathic drug definitions lists Arnica Montana Radix as monograph #0228 ARNR on Dec 1989 and it separately lists Arnica Montana as monograph #0229 ARNM on Sept 2004. “Arnica Montana” and “Arnica Montana Radix” are two separate and discrete drugs, and they are not interchangeable in HPUS Compendia or by FDA regulations. Thus, Traumeel® and Epicure do not contain “Arnica Montana” as an ingredient.

Traumeel® and Epicure contain five or six ingredients, respectively, whereas formulation (a) contains at least eight ingredients, Traumeel® and Epicure do not contain Bryonia Alba, which is required in formulation (b), and Traumeel® and Epicure contains Symphytum Officinale, which is excluded from formulation (c).

Thus, it is respectfully submitted that Traumeel® and Epicure do not anticipate claims 1 and 11-13. Accordingly, withdrawal of the rejection is respectfully requested.

III. Response to Rejection of Claims 1 and 10-13 under 35 U.S.C. § 102

Claims 1 and 10-13 is rejected under 35 U.S.C. §102(b) as allegedly being anticipated by <http://www.homeopathyhome.com/services/rshop/vshoppe/topicals.shtml> (X, Natural Health Products), as evidenced by the teachings of Internet Archive Wayback Machine (U1).

The Examiner cites Natural Health Products as teaching a formulation for topical use comprising Aconitum napellus 1x, Arnica montana 1X, Belladonna 1X, Hammamelis virginia 1X, Hypericum perforatum 1X, Ruta graveolens 1X and Symphytum officinale 1X in the form of a cream, which is used for the relief of pain and inflammation.

The Examiner appears to consider the above topical formulation to have appeared on the world wide web more than one year before filing date of the present application. Assuming such is the case, it is submitted that the Arnica Si Cream does not contain Bryonia Alba, which is required in formulation (b), only contains five ingredients whereas formula (a) requires at least 8 ingredients, and contains Symphytum Officinale, which is excluded from formulation (c). Hence, even if Natural Health Products did qualify as prior art, it does not anticipate claims 1 and 10-13. Accordingly, withdrawal of the rejection is respectfully requested.

IV. Response to Rejection of Claims under 35 U.S.C. § 103(a)

Claims 1 and 10-14, 19 and 20 remain rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over King Bio Natural Medicines (U) in view of Diec et al. (A*).

In addition, claims 1 and 11-14 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Epicure in view of Diec et al.

Applicant respectfully traverses the rejection for the reasons of record and for the following.

Initially, it is respectfully submitted that claims 1, 10-14, 19 and 20 are patentable over King Bio Natural Medicines or Epicure in view of Diec. Neither King Bio Natural Medicines nor Epicure teaches the topical formulation according to formulation (a), (b) or (c) for the reasons discussed above. In addition, Diec does not make up for the deficiencies of King Bio Natural Medicines or Epicure.

First, it is respectfully submitted that, for the reasons discussed above, the 911 Product is an oral formulation, not a topical formulation, and it would not have been obvious to one of ordinary skill in the art to use an oral drug for topical pain relief. In addition, since Diec does not

teach or reasonably suggest that an oral drug for internal stress can be modified as a topical analgesic pain relief, Diec does not make up for the deficiencies of King Bio Natural Medicines.

Furthermore, the disclosure relied upon by the Examiner regarding aerosol formulations relates to cosmetic deodorants. That is, col. 27, lines 5-10 states:

The cosmetic deodorants according to the invention can be in the form of aerosols, that is to say preparations which can be sprayed from aerosol containers, squeeze bottles or by a pump device, or in the form of liquid compositions which can be applied by means of roll-on devices, but also in the form of microemulsion gels which can be applied from normal bottles and containers.

Thus, one of ordinary skill in the art would not be motivated to add the microemulsion gel formulation to the 911 Product based on the teachings of Diec.

Second, contrary to the Examiner's position, Diec does not disclose the gel composition of the present invention.

Nowhere in Diec is the combined ingredients of the gel base of the present invention taught. Indeed, Diec contains 25 Examples of various formulations at column 43-45, yet none of the compositions are the same or similar to the gel base of the present invention, which comprises water, glycerine, a polyacrylic acid resin thickener, triethanolamine and methylparaben.

In addition, the principles of microemulsion gel formation of Diec is not used in the present invention and is entirely unrelated to the present invention. Diec relates to a cosmetic or dermatological preparations based on emulsifiers which are free from ethylene oxide and propylene oxide for the preparation of microemulsion gels, which is an oil in water microemulsion gels comprising a discontinuous oil phase and a continuous aqueous phase or oil-in-water microemulsion gels comprising lecithin or lecithin derivatives. *See* col. 1, lines 1-5; col. 46, line 41 and col. 48, line 11. In fact, Diec states, at column 7, line 50, that "Surprisingly,

all of the objects on which the invention is based are achieved by microemulsion gels (a) based on microemulsions of the oil-in-water type..."

In contrast, the gel base of the present invention contains no oils, and thus has no "discontinuous oil phase", and no emulsion or microemulsion or oil-in-water microemulsion. In addition, one of Diec's alternative microemulsions contains lecithin-an oil-containing phospholipid emulsifier. Soybean lecithin contains about 55% linolenic acid (Merck). The gel base of the present invention contains no lecithin with fatty acids or its derivatives. In this regard, by definition, emulsions are liquids dispersed in an immiscible liquid-usually larger than colloidal size. The gel base of the present invention does not contain an "immiscible liquid."

In other words, the heart of Diec is the formation of oil-in-water microemulsion gels. In contrast, the gel base of the present invention is a hydroalcoholic gel. It is a unique continuous phase homogeneous aqueous solution-a water soluble mixture. Carbomer only provides viscosity in a totally homogeneous hydroalcoholic solution, which does not contain a discontinuous oil phase nor does it even contain oil, or an immiscible liquid. The gel base of the present invention contains a highly volatile 40% ethyl alcohol constituent found in the alcohol and water tinctures, that are added to water which forms a unique hydroalcoholic homogeneous stable gel. Even though the base gel of the present invention uses a thickener, it is different from the thickening agent used in Diec's formulation, which is described as *"....crosslinking or thickening oil-in-water mico emulsions having a discontinuous oil phase..."* joining droplets with a hydrophilic and hydrophobic region forming a microemulsion. See col. 46, lines 63-65.

Furthermore, Diec describes the preparation of the microemulsion mixtures by
"*....heating said mixture, and then, with continued stirring, cooling the mixture at room temperature.*" See col. 21, lines 37-39. Diec also states that "*The microemulsion gels according to the invention advantageously comprise electrolytes, in particular one or more salts with the following anions...electrolytes based on organic anions can also advantageously be used, for example: lactates, acetates...*" See col. 26, lines 16-26; see also col. 26, lines 39-42 and Examples 1-25 (all utilize one or more of these electrolytes, or cations, or anions, or salts).

The gel base of the present invention is made by a process utilizing room temperature to prepare the gel-no heating and no cooling process is used. Heating the gel base mixture would in fact drive off the highly volatile alcohol constituent and destroy the gel stability of the present invention, preservation, and absorption. In addition, the gel base of the present invention does not contain microemulsion gels comprising electrolytes, salts or anions or cations. In fact, ingredients such as lactates, citrates, salts, etc. are known to seriously disrupt hydroalcohol gel stability, and such electrolytes would seriously disrupt or nullify the homeopathic medicinal action of the present invention, because of their disruptive electrical charges from which homeopathics should be protected, and would either elicit an additive, subtractive, or antidoting medicinal action.

Moreover, Diec describes glycerol and ethanol as "*cosmetic auxiliaries*" at column 32, lines 24-47. In other words, ingredient additives unessential to the formation of microemulsion oil-in-water gels.

The present invention uses ethanol as an important part of a novel hydroalcohol gel utilizing ethanol-water mixture further stabilized by ingredients in both the tincture in the gel

base, and without the presence of propyl or propylene molecules. The gel base of the present invention uses vegetable glycerine rather than regular synthesized glycerine derived from propylene; and substitutes for propylene glycol, which are harsher ingredients and less emollient and thus more pro-inflammatory: undesirable in a product which possesses anti-inflammatory properties. As disclosed in the present specification at [0021] on page 12, isopropyl alcohol or propylparaben should not be used (also avoid propylene glycol) in homeopathic formulations as propylene and propyl molecules are neurologically disruptive of energy function, and have a somewhat toxic nature, and much of homeopathic therapeutics depends on regulation through the nervous system. The gel base of the present invention is clear, and highly stable over about 4 years of testing and probably longer. The ethanol found in the present tinctures, and vegetable glycerine, becomes an integral part of the gel making process, not a "cosmetic auxiliary" as described in Diec, and helps build a highly preserved, extremely stable gel, absent propyl and propylene molecules and thus more therapeutically effective as evidenced by clinical testing.

For the above reasons, it is respectfully submitted that claims 1, 10 to 14, 19 and 20 are not unpatentable over King Bio Natural Medicines in view of Diec. Accordingly, withdrawal of the rejection is respectfully requested.

V. Conclusion

In view of the above amendments and remarks, reconsideration and allowance of claims 1-20, and rejoinder of claims 21-49 is respectfully requested.

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Application No. 10/797,009

Attorney Docket A9205

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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